From: "Wallace Jenkins" <jenkinsw@mrd.dnr.state.sc.us>, on 1/19/98 7:35 AM:
To: George Mitchell@OD@FDACVM

The request for comments on drug approvals ask a lot of questions the answers to which you could probably write extensive justifications for. I have listed the major questions in your summary document and provide brief responses to each. In general, I feel your agencies willingness to consider changes is a positive step. My answers should be considered with one unifying premise that is that I and others believe that fish should be divided into 4 subgroups Cold water or Warm water, marine or freshwater species. In other words if the research for a particular drug has been done for a freshwater species which is classifiesd as a warm water species then the results obtained should be applicable to other warm water species whihc live in freshwater. This may be an oversimplification from FDA perspective but it would eliminate having to obtain approval for every fish species.

Extralabel uses (fish)
Q1. The extralabel sunset clause is a good idea but at the rate things have progressed in the past 10 years may not be enough time.

Q2. yes hormones used to induce spawning should be included primarily because broodstock can be prohibited from entering the food change and their progeny will not enter the food chain for at least 6 months which should be an adequate withdrawal period considering the small doses to which individual embryos would have been exposed to.

Disincentives
Q1. I really do not have a feel for wheter the proposal will work or not but it would not hurt to try.

Q2. Again I do not know but based on the rate of NADA's in the past there are probably a lot more disincentives than have been identified in the current document.

Minor use research funding
Q1. This is a good idea although I am not sure where the money should come from.

NRSP-7
Q1. yes this cooperative relationship needs to be expanded

Database
Q1. I think it would be useful although the federal register is so loaded with extraneous information as to be useless to the average citizen. Having the info linked with the FDA home page and databases would probably make it more accessable to the people in the research community. I question whether a full time person is required to maintain such a database.

Incentives
Q1. I think it would be especially considering that there are currently few LEGAL compounds available at any price.

Q2. I do not work for a drug company but I have to believe that extended exclusivity would help. If and only if the other people selling the compound were effectively prohibited from doing so as described under disincentives.

Data Sharing
Q1. The cost of not doing so are already known (few if any approved compounds for minor species)

Q2. I do not know. No matter what you do any lawyer in the country can still sue and probably win a liability case.

Statutory designation
Q1. I guess I would ask if the orphan drug program has been benefical? If it has then this proposal probably would be also.

Minor use office development
Q1. I believe that they are necessary components.

Conditional Drug Approval
Statement: I think brood fish and early life stages when fish weigh almost nothing should be included with Zoo animals and pets in this section.

Q1.I believe they would provide plenty of consumer protection. I think it would provide an incentive especially if results from 1 species of fish could be used as a model to extrapolate effectiviness and residual data for other fish species thereby expanding the potential market for the product.

Q2. See above statement otherwise I agree with the restrictions outlined.

Expert Review panel
Q1. I believe that animal caretakers would find those standards acceptable if they did not they could choose not to use them.

Q2. In my opinion the expertise is present in the aquaculture indusrty to implement this process.

Q3. As I said above I think it should also include larval and fingerling fishes which are removed in time from the food fish population and for broodstock of food species because they do not enter the human food chain.

Harmonization
Q1. I think nn governmental imputs would be very valuable and should be part of the process.

Foreign
Q1 even if there is only 1 it would be more than we currently have and would be beneficial to industry.

Harmonization approval
Q1 yes
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